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| 10/802,180      | 03/17/2004  | Alan Brundle         | EIS-6128 (1417G P 815) | 3855             |

29200 7590 03/13/2007  
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| EXAMINER |
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FRANTZ, JESSICA L

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| ART UNIT | PAPER NUMBER |
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3746

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/13/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/802,180 | <b>Applicant(s)</b><br>BRUNDLE ET AL. |  |
|                              | <b>Examiner</b><br>Jessica L. Frantz | <b>Art Unit</b><br>3746               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11, 16, 17, 19, 20, 23, 24 rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. (4,855,660). Wright discloses the invention substantially as claimed including a sensor (20, 22) having an output; a motor controller (Microprocessor MPU, Figure 3A) having an output responsive to the sensor output, the motor controller configured to determine whether a motor controller output should account for the sensor output; a current driver (Q1, Q2, Q3, Q4) having an electrical current output responsive to the motor controller output; and a stepper motor (18) responsive to the electrical current output. Wright further discloses the sensor is responsive to changes in the position of the motor and the system includes additional sensors having outputs sent to the controller (Column 3, lines 3-11). Wright also discloses the controller has a memory containing data wherein the electrical current output is responsive to the data and the sensor output and the controller and memory are within a microcontroller. (Column 3, lines 40-45) and (Column 3, lines 3-11). Wright further teaches the application of micro stepping the motor as shown in figure. <sup>2??</sup> In regards to claim 17, while Wright makes no explicit mention of the fact that the motor controller is responsive to changes in the age of tubing used for administering medication, the controller of Wright does include a

memory as discussed above and is capable of storing the "age" of tubing used in a pumping application and it has been held that while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856). Wright teaches the invention substantially as claimed and as discussed above but fails to teach this method is used specifically for driving an infusion pump and includes the step of determining the position in a pump cycle, the step of determining a flow rate, and determining the electrical current value for driving the motor in response to the position in the pump cycle and the flow rate as separate factors and wherein the position in the pump cycle, the flow rate and the electrical current value are related to each other in a relationship database and wherein the position in the pump cycle and the flow rate are related to the

electrical current value. As discussed in the written description, the position in the pump cycle may be determined from a variety of sources one such being a database table stored in a computer or system memory and as discussed above, Wright teaches such a memory that stores data and therefore, is sufficient to determine the position in a pump cycle. Mulreany teaches a method 10 for driving an infusion pump including the step of determining a flow rate see figure 7, wherein the electrical current value output to the motor 298 is related to the flow rate and wherein the flow rate value is stored in a database (Column 2, lines 17-36) and (Column 7, lines 49 through Column 8, lines 1-23) (Also see Figures 5 and 7) for the purpose of maintaining a substantially constant selected flow rate. (Abstract). In regards to the limitation that the position in the pump cycle and the flow rate are added as separates factors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have separated the inputs in such a manner in order to allow the controller to be able to respond to just one of these two inputs in certain situations, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPO 177, 179. Furthermore, it has been held to be within the general skill of a worker in the art to select something known on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright et al. with the step of measuring fluid flow rate and comparing it to preset values stored in a controller

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database, thereby controlling an infusion pump motor, for the purpose of maintaining a substantially constant selected flow rate. (Abstract).

5. Claims 12, 13, 14, 15, 21, 22, 25, 26, 27, 28, 29, 31, 32, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Moberg et al. (6,659,980). Wright is discussed above and teaches the invention substantially as claimed but fails to teach the stepper motor is contained within an infusion pump under battery power wherein the output of the sensor is responsive to temperature changes and wherein the output of the sensor is sensitive to backpressure changes. Moberg teaches the stepper motor is contained within an infusion pump (101) (Column 2, lines 52-55) for the purpose of providing power to the pump. Moberg further teaches the preferred power supply is one or more batteries (Column 7, lines 39-40) for the purpose of allowing the device to be compact and wearable by the user. (Column 1, lines 61-67). Moberg further teaches the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body. (Column 6, lines 6-14) and (Column 9, lines 18-45). Moberg also teaches the output of the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Wright et al. with the teachings of Moberg et al. including the stepper motor being contained within the infusion pump for the purpose of providing power to the pump (Column 2, lines 52-55) and the power supply is one or more

batteries (Column 7, lines 39-40) for the purpose of allowing the device to be compact and wearable by the user (Column 1, lines 61-67) and also the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body (Column 6, lines 6-14) and (Column 9, lines 18-45) and that the output of the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25).

6. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856) and further in view of Moberg et al. (6,659,980). The combined invention of Wright and Mulreany is discussed above, however they fail to teach the step of modifying the electrical current value in response to temperature information or distal pressure information. Moberg et al., as discussed above teaches the output of the sensor is responsive to backpressure changes for the purpose of detecting occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body. (Column 6, lines 6-14) and (Column 9, lines 18-45). Moberg also teaches the output of the sensor is responsive to temperature changes for the purpose of ensuring an accurate reading from the backpressure sensor (Column 19, lines 21-25) and the method of using the combined invention of Wright, Mulreany and Moberg is obvious given the structure. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright and Mulreany with the step of modifying the electrical current value in response to the output of a pressure sensor in

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order to of detect occlusions in the fluid path that slow, prevent, or otherwise degrade fluid delivery from the reservoir to the user's body (Column 6, lines 6-14) and (Column 9, lines 18-45) and also in response to a temperature sensor in order to ensure an accurate reading from the backpressure sensor (Column 19, lines 21-25).

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856) and further in view of Harriman et al. (US PG PUB 2003/0235409). The combined invention of Wright and Mulreany is discussed above but fails to teach the step of modifying the electrical current value in response to an elapsed time value or in response to the age of the infusion pump motor. Harriman teaches modifying the electric current value in response to an elapsed time value in order to determine whether or not to set the motor at an "ambient state." (Paragraphs [0016] and [0017] and Figure 4B) and also in response to the age of the infusion pump motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright and Mulreany with the steps of modifying the electrical current value in response to an elapsed time value and in response to the age of the infusion pump motor in order to determine whether or not to set the motor at an "ambient state." (Paragraphs [0016] and [0017] and Figure 4B) and to ensure the proper motor performance (Paragraphs [0015] and [0016]).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Mulreany et al. (4,838,856) and further in view of Maske et al.

(6,208,107). Wright is discussed above but fails to teach the step of half stepping the infusion pump motor. Maske teaches the step of half-stepping the motor in order to reduce excitation energy to approximately 29% of the full-step energy. (Column 3, lines 47-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright with the step of half stepping the motor in order to reduce excitation energy. (Column 3, lines 47-51)

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Harriman et al. (US PGPUB 2003/0235409). Wright is discussed above and fails to teach the motor controller is responsive to changes in the age of the motor. Harriman teaches the motor controller is responsive to changes in the age of the motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the invention of Wright with ability of the motor controller to be responsive to the age of the motor in order to ensure the proper motor performance. (Paragraphs [0015] and [0016]).

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (4,855,660) in view of Moberg et al. (6,659,980) and further in view of Harriman et al. (US PGPUB 2003/0235409). The combined teachings of Wright and Moberg fail to teach the motor controller is responsive to changes in the age of the motor. Harriman teaches the motor controller is responsive to changes in the age of the motor in order to ensure the proper motor performance (Paragraphs [0015] and [0016]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to

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have provided the invention of Wright and Moberg with ability of the motor controller to be responsive to the age of the motor in order to ensure the proper motor performance. (Paragraphs [0015] and [0016]).

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection due to Applicant's amendment.

12. Regarding Applicants argument that Wright does not mention a pump motor or pump cycle as claimed in claim 1, Examiner kindly directs Applicant's attention to the new grounds of rejection as discussed above where claim 1, is rejected under Wright in view of Mulreany.

13. In regards to Applicants arguments that the electrical current value is responsive to the position of the pump cycle and the flow rate as separate factors, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have separated the inputs in such a manner in order to allow the controller to be able to respond to just one of these two inputs in certain situations, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPO 177, 179. Furthermore, it has been held to be within the general skill of a worker in the art to select something known on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

14. In regards to Applicants argument that none of the references teach a motor controller configured to determine whether a motor controller output should account for

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a sensor output, as the sensors of the applied references are outputting to their respective controllers, the controllers are then able to choose whether or not to account for the sensors output. For example, as shown in Wright, if the sensors 20, 22 which output to the controller MPU return a sensed value that equates to zero change, the controller chooses not account for the sensed output. Furthermore, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. Since the controller of Wright is capable of being configured in such a manner via its memory, it meets the recited limitations.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Frantz whose telephone number is 571-272-5822. The examiner can normally be reached on Monday through Friday 8:30a.m.-5:00p.m. E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on (571) 272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Jessica Trantz*

JF 3/5/2007

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